

## CHAPTER 3. PROGRAMS AND PROGRAM REVIEW

### 3.01 PROGRAM ORIENTATION

a. The Rehab R&D Service encourages investigators to explore problems of interest to them but certain areas of endeavor are of special interest to the VA. The VA Central Office identifies these high priority areas and notifies the health care facilities and Rehab R&D Centers when additional support is available for projects so identified. Proposals within these special areas are submitted and evaluated for scientific and technical quality as are other Rehab R&D proposals.

b. Rehab R&D projects that are developmental, device-oriented, or that deal with evaluation must be scientifically as well as technically meritorious. All projects must follow approved protocols and be consistent with VA Regulations and policies and other pertinent laws and regulations. The Food and Drug Administration has requirements for experimental devices similar to those for experimental drugs (see 21, CFR 812.) The VA requires adherence to these regulations and requires the local R&D Committee and Human Studies Subcommittee to review Rehab R&D programs for compliance with them.

c. Well-controlled evaluation projects are critical to the success of the Rehab R&D programs. They should be objective, well-documented clinical studies with adequate controls for comparison even when they cannot be classical double-blind, random-application experiments. An evaluation protocol will be established, reviewed, and approved before the testing and must be adhered to in the same manner as are other research protocols.

d. Clinical Rehab R&D investigations, including cooperative and collaborative studies, are encouraged. Their initiation and conduct follow the procedures used for other types of research and development. (See pt. 1, chs. 3 through 5, 8 and 9, and pt. 11, par. 3.05.)

### 3.02 PROGRAM REVIEW

a. In VA health care facilities with R&D Committees, professional staff members in prosthetics treatment centers, orthotics laboratories, clinics, medical centers, and similar facilities submit Rehab R&D research proposals to the local R&D Committee through the ACOS/R&D. The principal investigator prepares a detailed research proposal that the local research office reviews for format and completeness. The R&D Committee and its Human Studies Subcommittee evaluate the proposal as they do other R&D proposals and recommend action to the facility Director. The latter forwards any approved proposals with the R&D Committee's recommendation to the Director, Rehab R&D Service, for scientific review and consideration for funding.

b. Rehab R&D proposals submitted to VA Central Office for merit review are evaluated by the Scientific Review and Evaluation Board for Rehab R&D. The Board makes recommendations to the Director, Rehab R&D Service regarding the scientific quality, level of support and relevance to the Rehab R&D Service's mission and priorities. In addition to scientists and experts chosen for their experience, Knowledge and research involvement in the various rehabilitation areas, membership of the Board includes consumer representatives from various veterans service organizations. The decision of the Director, Rehab R&D Service regarding the Board's recommendations is transmitted to the health care facilities along with review results and supporting documentation.

c. A Rehab R&D Center submits a proposal for each new program in the same manner as other proposals; i.e., through the ACOS/R&D, R&D Committee and the facility Director to the Director, Rehab R&D Service.

### 3.03 RESEARCH ADVISORY GROUP REVIEW

Requests for Rehab R&D funding submitted to VA Central Office for RAG (Research Advisory Group) review must be routed through the Director, Rehab R&D Service, the R&D Committee, and the facility Director before consideration by the RAG. If all concur that the request is appropriate for RAG review, the RAG will process the request and provide its recommendations to the Director, Rehab R&D Service for consideration. (See pt. 11, par. 3.02.)

### **3.04 CAREER DEVELOPMENT PROGRAM**

Rehab R&D Service may participate in the R&D Career Development program as described in part 11, paragraph 3.04. Any requests for Rehab R&D participation will be submitted to the Director, Rehab R&D Service for review and approval prior to processing by the Career Development Program of Medical Research Service as described in part 11, paragraph 3.04.

### **3.05 COOPERATIVE STUDIES PROGRAM**

If funding support will be requested from Rehab R&D Service, any cooperative study proposed in rehabilitation R&D shall be submitted to the Director, Rehab **R&D** Service for review and approval prior to processing by the Director, Cooperative Studies Program in accordance with procedures described in part 11, paragraph 3.05.

### **3.06 RESEARCH CAREER SCIENTISTS**

Any requests for research career scientist appointments of Rehab R&D investigators shall be routed through the Director, Rehab R&D Service for concurrence prior to submission to the Medical Research Service for processing in a manner analogous to that for biomedical researchcar-eer scientists. (See pt. II, par. 3.06.)